OCT - 1 2001

K012466

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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

July 31, 2001

Submitter:

GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Karen Webb
Sr. Regulatory Affairs Specialist
GE Medical Systems Information Technologies
Phone: (414) 362-3329
Fax: (414) 918-8114

Device: Trade Name:

BIS/EEG Module

Common/Usual Name:

Electroencephalograph (EEG)

Classification Names:

21 CFR 882.1400 Electroencephalograph

Predicate Devices:

K974496, K923043 & K011843 Aspect Medical Systems, Inc. EEG Monitor with BIS Engine

Device Description:

The BIS/EEG Module is part of a modular system used to monitor the state of the brain by data acquisition of EEG signals. The module is also used as an aid in monitoring the effects of certain anesthetic agents using Aspect's Bispectral Index® parameter.

BIS/EEG Module works as a component of a GE Medical Systems Information Technologies host monitoring system and does not function on its own. The BIS/EEG Module provides information obtained from the sensors/electrodes to the bedside monitor for display.

Intended Use:

The BIS/EEG Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS/EEG Module is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS/EEG Module is intended to monitor the Bispectral Index (BIS), a processed EEG variable which may be used as an aid in monitoring the effects of certain anesthetic agents.

Technology:

The BIS/EEG Module employs the same functional scientific technology as its predicate device.

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Test Summary:

The BIS/EEG Module and its host patient monitoring system comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the BIS/EEG Module:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the BIS/EEG Module is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Ms. Karen Webb
Senior Regulatory Affairs Specialist
GE Medical Systems
Information Technologies
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K012466
Trade/Device Name: BIS/EEG Module
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: July 31, 2001
Received: August 1, 2001

Dear Ms. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012466; 510(k) filed on July 31, 2001

Device Name: BIS/EEG Module

Indications for Use:

The BIS/EEG Module is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS/EEG Module is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012466